K010395

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510(k) SUMMARY
Dalton Medical Corporation
E-POWER
2/01/01

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k), premarket notification was in accordance with 21 CFR, Section 890.3860 and SMDA.

1. Submitter of 510(k):

Contact Person:	Will Ridgway
Company Name:	Dalton Medical Corporation
Address:	1103 Venture Ct. Carrollton, TX 75006 U.S.A.
Phone:	(972) 418-2447
Fax:	(972) 418-5706

2. Name Of Device: E-POWER

Common/Usual Name: Wheelchair, powered

Classification Name: In accordance with FDA's manual, "Classification Names For Medical Devices And In Vitro Diagnostic Products" and FDA's listing of prior 510(k) clearances, predicate devices were assigned to classification 21 CFR, Section 890.3860 "WHEELCHAIR, POWERED".

3. Reason For Submitting The 510(k):

Dalton Medical Corporation wishes to commercially distribute its new "E-Power" device to provide mobility to persons limited to a seated position that are capable of operating a power wheelchair.

4. Device Description:

The E-POWER model is comprised of foldable wheelchair, battery powered, motor driven device with the intended function and use of providing mobility for those persons limited to a seated position that have capability to operate powered wheelchair. A Dynamic DL joystick and controller are used to operate E-POWER. It is powered by two U1 (31ah), batteries and has a range

of up to 20 miles on a full charge. The base chair is made of welded steel construction. Seating material meets California 117 standards for fire retardancy.

5. Intended Use:

The intended use of the E-POWER is to provide mobility to persons limited to a seated position that are capable of operating a powered wheelchair.

6. Substantial Equivalence:

E-POWER is equivalent in use to MP-1 (K933662) from Merits Health Products device that already exists in the market. They both have **exactly the same** parts and made by the same company, - Merits Health Products. Merits Health Products will private label the same wheelchair for Dalton Medical under the name **E-POWER.** All safety features are equivalent.

Since E-Power has the same intended use, safety and effectiveness as the legally marketed predicate devices, it is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2001

Mr. Will Ridgway
National Manager
Dalton Medical Corporation
1103 Venture Court
Carrollton, Texas 75006

Re: K010395
Trade Name: E-Power
Regulation Number: 890.3860
Regulatory Class: II
Product Code: ITI
Dated: April 10, 2001
Received: April 10, 2001

Dear Mr. Ridgway:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Barbara Zimmerman for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010395

Device Name: E-Power

Indications For Use:

The intended use of the E-Power is to provide mobility to persons limited to a seated position that are capable of operating a powered wheelchair.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Zimmerman for Dr. Witten

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number ______

Prescription Use ______
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)